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RESEARCH ARTICLE

Development of Blockchain-Based Health Information Exchange Platform Using HL7 FHIR Standards: Usability Test

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This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the Institutional Review Board (IRB) of the Seoul National University Hospital under IRB No. H-2008-069-1147.

ABSTRACT Health information exchange can improve health outcomes and reduce unnecessary medical expenses. An important task in health information exchange is to prove data integrity and strengthen the right to self-determination of individuals. This can be addressed using blockchain technology and dynamic consents. We aimed to develop a blockchain-based mobile platform called HealthPocket to exchange reliable health information with proven integrity through a dynamic consent system based on the HL7 FHIR standards. Through HealthPocket, subjects can selectively provide their consent to share specific medical and PGHD through proper authorization, and each response is converted into the JSON format with FHIR compatibility. We conducted a usability test to demonstrate health information exchange between primary and tertiary medical institutions. A total of 116 subjects used the HealthPocket mobile application to selectively share health information for at least one month, and conducted a questionnaire about their experience. In addition, medical staff of the institution could access the medical information shared by the participants and use it for treatment. The user surveys for patients examined the perceived usefulness, perceived ease of use, and overall service satisfaction. The mean overall satisfaction with the health information exchange service was the highest (4.67 out of 5 points). As security, personal information protection, and interoperability are main concerns related to health information exchange, blockchain technology can provide suitable solutions. For instance, when health information is exchanged using blockchain technology, it is impossible to alter data blocks. Therefore, by using a blockchain-based platform and dynamic consent system, we ensured the integrity of medical data.

INDEX TERMS Blockchain, dynamic consent, fast healthcare interoperability resources, health information exchange, mobile application, personal health record.

I. INTRODUCTION

The healthcare paradigm is evolving toward patient-centered care continuity [1], [2]. In particular, health information

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exchange can enhance patient-centered care through the continuity of treatment by electronically linking medical information scattered across medical institutions [3]–[6]. Furthermore, health information exchange can help strengthening the patient's right to self-determination, efficiency of medical delivery, establishment of medical big data, and introduction of health management services [7]–[10].

For improving medical efficiency or revitalizing the digital health industry relying on personal health records, the integrity of health information exchange must be proved, and extensive research is being conducted on this topic [11], [12]. When creating new knowledge and industries based on exchanged health information, personal information should be protected, and the right to self-determination of patients should be strengthened [6]. Data integrity and secured self-determination can be implemented using blockchains and related dynamic consents [13]. A dynamic consent is a blockchain technology based on a protocol that enables patients to directly control their data and consents [13], [14].

When medical information is shared between healthcare institutions, interoperability among different electronic health record (EHR) systems with various terminology standards and data integrity may be difficult to achieve [12], [15]–[18]. On the other hand, when using blockchain to store and share medical information, the data blocks cannot be altered. In addition, data blocks are connected and stored in a chain according to their order of occurrence, resolving problems related to data authenticity or redundancy, which may occur when data are shared between multiple medical institutions [11], [19], [20].

Existing studies have mainly focused on blockchain technology for interoperability and integrity of personal health data [21], [22]. In this study, we aimed to develop and demonstrate a blockchain-based mobile platform, called HealthPocket, to exchange reliable health information with proven integrity through a dynamic consent system that guarantees the right to self-determination of individuals based on the HL7 FHIR (Health Level 7 Fast Healthcare Interoperability Resources) standards.

II. METHODS

A. STANDARDIZATION OF HEALTH INFORMATION USING FHIR

When a patient encounters a healthcare service, the providers may want to access the patient's health records to initially assess the health condition. Patients have the right to decide and select which records to share. After obtaining the patient consent, data exchange between hospitals must be efficient and secure through an interoperable communication framework. We used the HL7 FHIR for interoperability standards, since it has extensible capabilities to contain all data entities from both patient-generated health data (PGHD) and EHRs. In addition, data communication is based on the RESTful protocol to exchange data across various types of systems [23]. To illustrate the structural interoperability and dynamic consents, we selected specific data elements in an EHR (e.g., observation results of complete blood count, renal tests, medication prescriptions) and PGHD (e.g., data acquired through wearable devices and their application programming interfaces—APIs). For the selected data, FHIR was profiled with optimized resource attributes, and the reusability of the resources was tested and validated across an external server provided by the HL7 Parser and API (HAPI) library [24].

B. BLOCKCHAIN FOR HEALTH INFORMATION EXCHANGE

1) SYSTEM ARCHITECTURE

Figure 1 shows the service model architecture of the system. The data of the EHR (or PGHD) in the application of the patient/practitioner are connected to a blockchain to prove data integrity and exchanged using FHIR in the JavaScript Object Notation (JSON) format for structural interoperability. For the patient's mobile application (app), their data are collected with the request from the hospital or PGHD platform through proper authorization, and each response is converted into the JSON format with FHIR compatibility. In the first encounter between a practitioner and patient, the practitioner can request consent from the patient to share data.

Once the patient provides consent through the app to the practitioner for selected data, which the patient agrees to share, the practitioner can receive these data in a desktop application. In this service model, all the user-consented data are connected to a blockchain and have FHIR compatibility. Hence, data can be shared and integrated into various healthcare services designed in conformance with FHIR while ensuring data integrity.

2) BLOCKCHAIN

The system uses the MediBloc Panacea blockchain network [25], which was developed based on the Tendermint blockchain [26]. This blockchain uses the delegated proof-of-stake method implemented using Byzantine fault tolerance to create blocks. In this system, delegated nodes perform and validate the transactions and blocks. The validators are selected by voting. Typically, one block is generated per second, and the transaction history is transmitted over the network and stored in the generated block. Furthermore, like other blockchains, once created, the blocks cannot be altered. The blockchain project freely composes the transaction data model using data such as hash values.

III. USABILITY TEST

A. SERVICE TO USERS

Participants downloaded and used the HealthPocket app for at least one month to evaluate our solution. The app can show information from wearable devices, check EHRs from medical institutions, and share or withdraw personal data. Either a Fitbit Inspire2 (Fitbit, San Francisco, CA, USA) or Miband 4 (Xiaomi, Beijing, China) was provided to each participant. The study was performed in accordance with the Declaration of Helsinki, the international

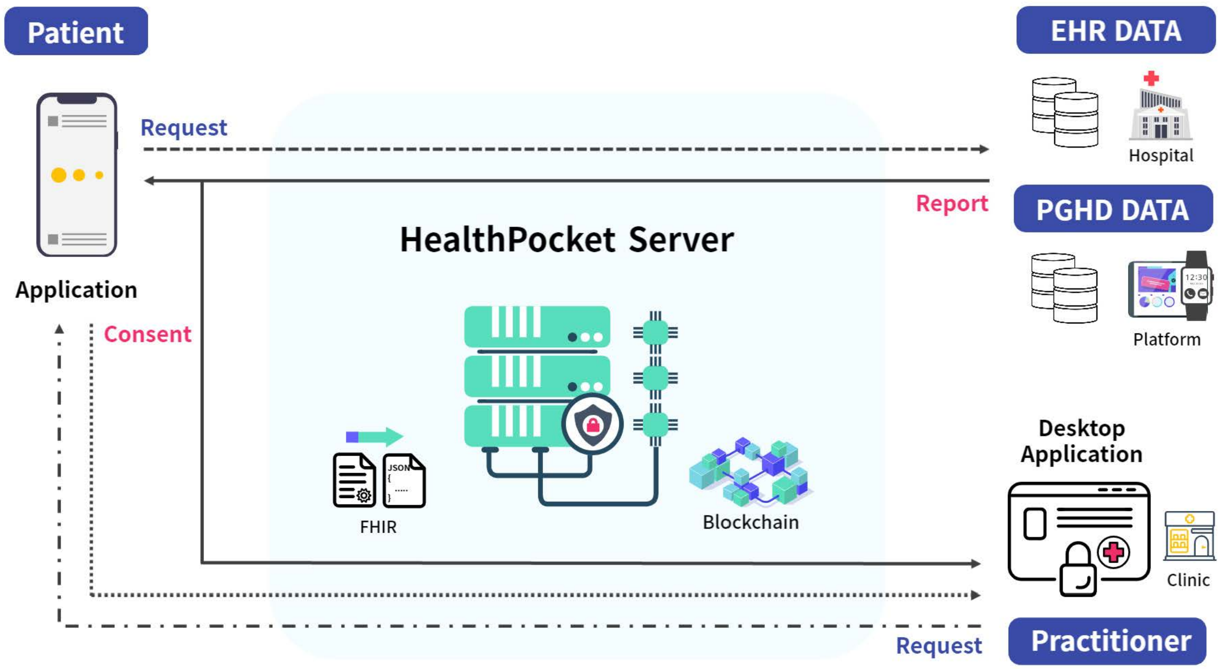

FIGURE 1. Service model architecture of HealthPocket platform with FHIR standards and blockchain technology.

conference on harmonization-good clinical practice (ICH-GCP), and the Korean good clinical practice (KGCP). The study was approved by the institutional review board of Seoul National University Hospital (SNUH) (approval no. H-2008-069-1147), Republic of Korea.

B. PARTICIPANTS

Any person who had been treated at SNUH or Maseok-Asan Clinic at an age over 20 years was eligible to participate in this study. SNUH is a non-profit academic referral government hospital with 1778 beds. Maseok-Asan Clinic is a primary care clinic in Namyangju city, Gyeong-gi province, Republic of Korea. We conducted an online survey to evaluate the overall user satisfaction with our HealthPocket app. We explained the research and obtained informed consent from the individuals who agreed to participate in the study.

C. USER SURVEY

The user surveys examined the perceived usefulness, perceived ease of use, and satisfaction with the HealthPocket service. The perceived usefulness is a subjective belief that the productivity and efficiency of work will increase by introducing a new technology or system. The perceived ease of use is the subjective belief that using a new system will not require much mental and physical effort. The participants rated their level of perceived importance according to a 5-point Likert scale of strongly disagree (1), disagree (2), undecided (3), agree (4), and strongly agree (5) [27]. The online questionnaire also included open-ended questions about the advantages and limitations of the platform. The questionnaires were administered through an online Google survey form. The participants could access the questionnaires through a web link and completed the survey at any time or place, thereby ensuring privacy and promoting honesty in their responses. We used coefficient alpha (Cronbach's alpha) to measure the internal consistency of the survey [28].

IV. RESULTS

A. STANDARDIZATION OF HEALTH INFORMATION WITH FHIR

We profiled FHIR from the HL7 repository and encoded to optimized resources for the selected data entities in our HealthPocket system, envisioning its wide use in various systems conforming with FHIR. After obtaining patient's consent for sharing diagnostic test results, our server provided interfaces with hospital databases via the EHR API and then acquired data encoded in FHIR (diagnostic report). Similarly, PGHD (e.g., total step count, walking distance, and consumed calories) retrieved from wearable devices were encoded into suitable FHIR instances to reflect the data type. Data gathered from these actions, mostly packaged as a set of Bundle Resources, in the JSON format are shown in Supplementary Figure 1.

B. HEALTHPOCKET PLATFORM FOR PATIENTS AND PHYSICIANS

The participants were able to check their medical information and various lifelog data acquired from the wearable devices through the HealthPocket app. They were also able to selectively transmit their health related data to medical staff if necessary. The lifelog collection and transmission of medical information were selectively performed with the voluntary

TABLE 1. Characteristics of study participants and service use.

		Number (%)
Number of participants		116
Women		75 (64.7%)
Used service	Inquire about medical records	116 (100%)
	Inquire about lifelog data	116 (100%)
	Share health information	8 (6.9%)

TABLE 2. Perceived ease of use and perceived usefulness.

Survey item	Respondents (n = 105)	
	Mean	SD
Perceived ease of use		
Is it easy to understand the terms of service?	3.82	0.90
Are your data usage results easy to understand?	3.68	1.03
Perceived usefulness		
Does this service provide useful information/functions to you?	3.79	0.96
Are you willing to continue using this service?	3.53	1.07

consent of the involved parties (Figure 1). The transmitted medical information was not stored in the medical information system of each medical institution. Instead, the medical staff were only able to visualize shared information through the app (Figure 2).

C. USABILITY TEST

The usability test was conducted from October 2020 to June 2021 with 116 participants (75 women, 64.7%; age of 41.7 ± 9.8 years) evaluating the HealthPocket app. Eight participants were enrolled from Maseok-Asan Clinic, and 108 were enrolled from SNUH. Maseok-Asan Clinic, as a primary medical institution, receives patients in need of treatment at tertiary hospitals. The 8 patients included in this study were referred to the family medicine clinic of SNUH (Table 1). Participants used the app at least one month, and no one had been dropped out in the middle of the study. Physicians from SNUH and Maseok-Asan Clinic checked the medical information selectively shared by each patient through the HealthPocket app. Depending on the patient's selectively shared information, the physician could check EHRs including information such as diagnosis and medication or lifelog information, such as step count, calorie consumption, and physical activity.

A total of 105 participants took part in the survey. For the usability test, the mean perceived ease of use showed the highest score, with 3.82 out of 5 points (perceived ease of understanding regarding service contents), while the mean perceived usefulness scored 3.79 (providing useful information and functions to users), as detailed in Table 2. The reliability coefficients were 0.84 and 0.87 for the perceived ease of use and usefulness, respectively. Table 3 lists the satisfaction survey results. The mean overall satisfaction with the health information exchange service scored 4.67, and its reliability coefficient was 0.78.

TABLE 3. Satisfaction with health information sharing service.

Survey item	Respondents (n = 6)	
	Mean	SD
Is the consent system for sharing health information easy to understand?	4.50	0.55
Are the personal information provision consent (partial, full) instructions for health information exchange easy to read?	4.67	0.52
Please evaluate your satisfaction with the health information exchange service	4.67	0.52

V. DISCUSSION

In this study, we developed and demonstrated a platform that enables individuals to proactively use and share their health information. Each item of PGHD was converted into the HL7 FHIR format to achieve data standardization. In addition, by uploading the converted data to a blockchain platform, forgery and falsification of data is impeded to ensure data integrity. Reliable health information was exchanged based on the consent of the individual, who ensured the right to self-determination through dynamic consents implemented in the HealthPocket app. A total of 116 people participated in a usability test, with 8 of them being patients referred from a primary medical institution to a tertiary medical institution, who were able to use the health information exchange service between the medical institutions.

A. USE OF BLOCKCHAIN IN HEALTHCARE INFORMATION EXCHANGE

Although the adoption rate of EHRs is rapidly increasing in many countries [29]–[31], it is still difficult to comprehensively use health information including lifelog data. However, health information exchange is more limited owing to concerns regarding security, personal information protection, and interoperability, and it has not been implemented properly [32]–[34]. Blockchain technology can provide a solution to these problems. When health information is exchanged through a blockchain, it is impossible to alter data blocks, which are connected and stored in a chain according to their occurrence order. Thus, data integrity is ensured and redundancy is mitigated, especially when sharing data between multiple medical institutions [35]–[39]. In addition, no centralized server is required, and data blocks are created with timestamps when recording. As a data block is verified by all nodes participating in the peer-to-peer network before storage in the blockchain, data security may be strengthened

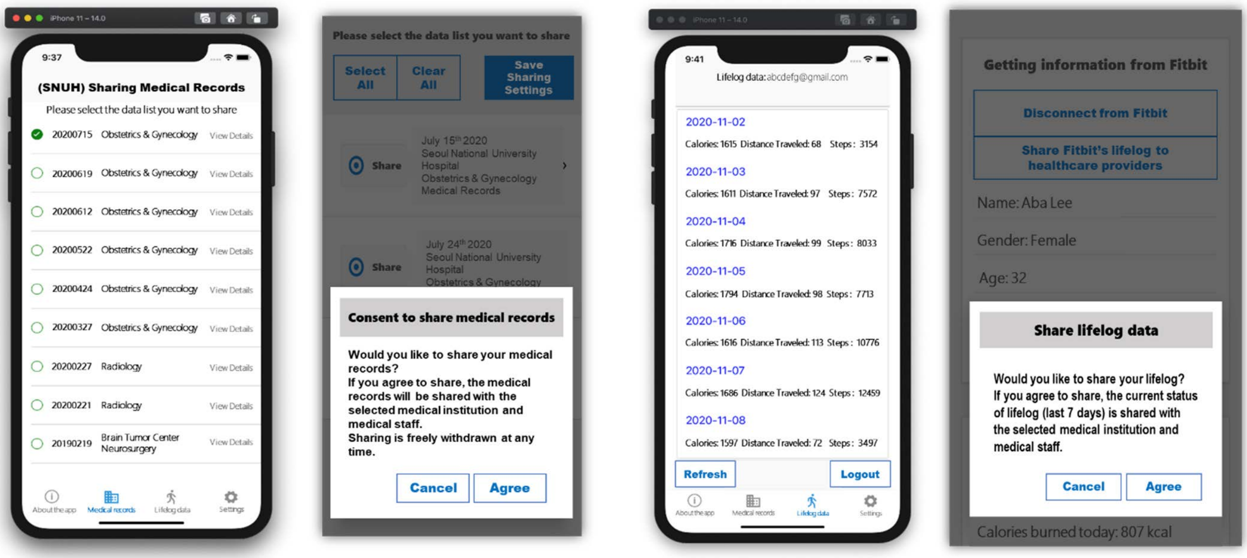

FIGURE 2. Sharing interface for EHRs and lifelog data through HealthPocket app.

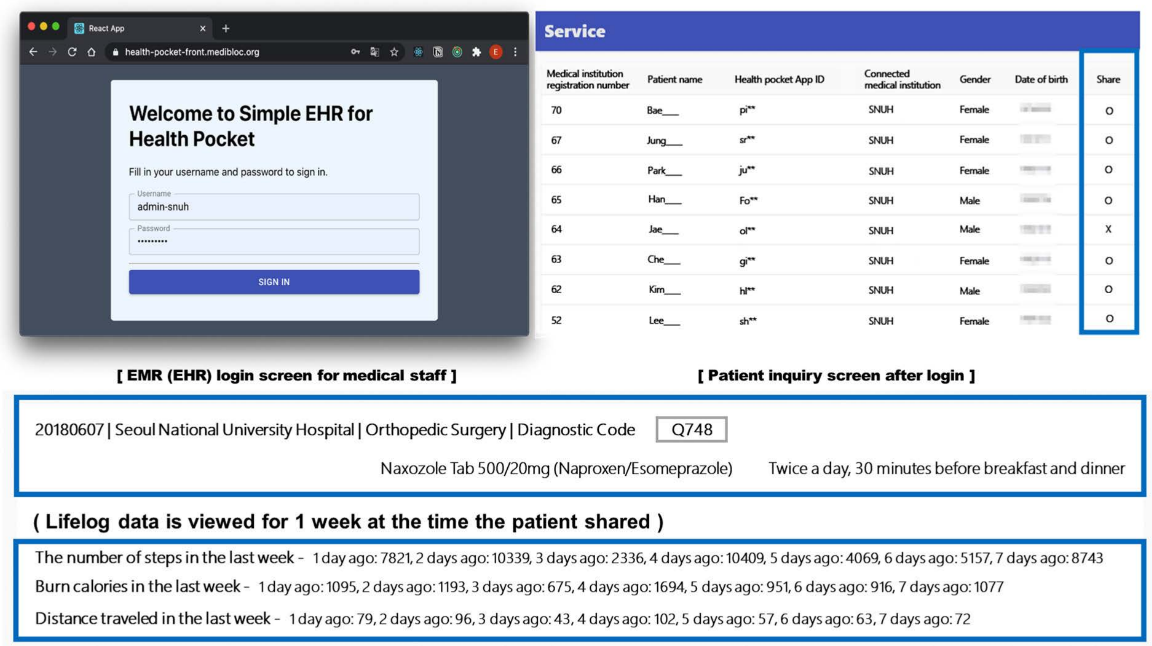

FIGURE 3. Data visualization though HealthPocket app.

[40]. Meanwhile, providing consent and ensuring data reliability have limited the implementation of adequate health information exchange [41]. We used the blockchain-based HealthPocket platform to ensure the integrity of medical data while allowing dynamic consent provision. Dynamic consent is a personalized and interactive consent protocol that allows individuals to set consent preferences for data to share with various healthcare providers [14]. It allows people to control their health data by granting and revoking access to it by third parties and tracking and updating consent as desired [13], [14].

Health information exchange can reduce unnecessary medical expenses [42] and contribute to improve health outcomes [43]. One case of HealthPocket usage illustrates improving health outcomes through health information exchange. A 58-year-old man was treated for hypertension, dyslipidemia, and diabetes with his primary physician working at Maseok-Asan Clinic. The week before examination, he had a chest pain that lasted several minutes. His primary physician referred him to SNUH through the HealthPocket app. Additional tests conducted at SNUH revealed a positive treadmill test and severe coronary stenosis with total occlusion through coronary computed tomography angiography. The patient was hospitalized and received a coronary bypass graft surgery, being subsequently discharged without complications. Even after the patient was discharged from SNUH and returned to the community, his primary physician was able to check the patient's SNUH medical records through the HealthPocket app and used the information for patient care, improving care continuity.

B. HEALTH INFORMATION STANDARDIZATION WITH FHIR

As our study has been focused on empowering patients through the developed HealthPocket platform to participate and control their data in the health system, it is necessary to use a data format that is common and simple to understand for the public. We selected HL7 FHIR standards for health information standardization because of their flexibility for programming languages such as eXtensible Markup Language (XML), JSON, and Resource Description Framework (RDF) and their ability to adopt the Representational state transfer RESTful protocol with APIs suitable for most modern web-based systems [44]. The flexibility between languages in FHIR allows to keep adequate syntax rules in legacy research (e.g., conversion between RDF and Clinical Document Architecture (CDA) formats or Archetype and XML) while enhancing simplicity and interpretability regarding the structural interoperability standards for developers and other parties. Most modern systems are designed to promote the reusability of data through APIs for data exchange in various applications. The support of the RESTful protocol with APIs in FHIR is the simplest way to achieve efficient and interoperable data control without requiring full understanding of the developed platform and its architecture. In addition, as FHIR is an open-source standard, anyone with sufficient knowledge in programming languages and data exchange can conveniently implement solutions for standardizing health information.

During data conversion into FHIR standards, we discovered different demands of developers and clinicians about data elements to be included in the data exchange structures. However, data elements defined in FHIR can cover almost 80% of real-world data, except for questionnaires and responses [45]. Thus, we could derive structure rules (templates) to include the selected data entities in FHIR with simplicity while satisfying the needs of clinicians and patients in the HealthPocket platform. To include more types of PGHD from users, we are continuously extending our FHIR profiling and deriving simple structure rules for implementation. In future work, we will extend the FHIR profiles and provide API documentation for following FHIR templates online while optimizing programming, such that health information can be easily and safely exchanged anytime and anywhere.

C. STRENGTHS AND LIMITATIONS

This study conducted a user survey on patients who used the HealthPocket application for more than a month. The most remarkable strength of the HealthPocket platform is that health information of a patient could be shared seamlessly between medical institutions, likely contributing to care continuity and the improvement of health outcomes. In addition, the right to self-determination is ensured by allowing individuals to independently manage their health data and selectively and interactively share information using dynamic consents. By adopting FHIR and deriving optimal format logic to encode data entities with simplicity, we can achieve structural interoperability with other systems or applications in conformance with FHIR. The outcome of data exchange in FHIR formats in our platform has satisfied both patients and clinicians.

One limitation of this study is related to the low scores of perceived ease of use and usefulness, which reached only 3.5–3.8 out of 5 points. Thus, another strategy is required to increase usability. In addition, the system is currently implemented between two specific medical institutions and remains part of a pilot study relying on independent web applications rather than actual EHRs. For proper health information exchange, we will upgrade the platform for standardizing and linking to EHRs and making it available to different medical institutions.

VI. CONCLUSION

We propose a blockchain-based health information exchange platform based on HL7 FHIR Standards. The adoption of blockchain technology may increase the users' confidence in exchanged data by mitigating problems related to security, privacy, and trust. By leveraging HL7 FHIR, the HealthPocket platform can reuse data for a variety of applications with pervasive and standardized components.

AUTHORS' CONTRIBUTIONS

Hyung-Jin Yoon and Ye Seul Bae had full access to all the data in the study and was responsible for data integrity and the accuracy of data analysis. Ye Seul Bae, Yujin Park, Seung Min Lee, Sang Min Park, and Taehoon Ko conceived and designed the study. Ye Seul Bae, Hee Hwa Seo, and Hyeonji Lee acquired, analyzed, and interpreted the data. Ye Seul Bae, Yujin Park, and Seung Min Lee drafted the manuscript. Critical revision of the manuscript was provided by Hyung-Jin Yoon and Sang Min Park. Ye Seul Bae, Yujin Park, Seung Min Lee, Taehoon Ko, and Eunsol Lee provided administrative, technical, or material support.

INFORMED CONSENT STATEMENT

Informed consent was obtained from the participants before the study.

DATA AVAILABILITY STATEMENT

Data related to this study are not publicly available.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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